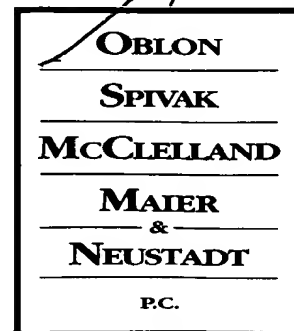




Docket No.: 202820US3

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313



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RE: Application Serial No.: 09/783,548
Applicants: Tomoshige UMEDA, et al.
Filing Date: February 15, 2001
For: MASK
Group Art Unit: 3749
Examiner: BASICHAS, A.

RECEIVED

MAR 17 2004

TECHNOLOGY CENTER R3700

SIR:

Attached hereto for filing are the following papers:

Appeal Brief (in triplicate)

Our credit card payment form in the amount of **\$330.00** is attached covering any required fees. In the event any variance exists between the amount enclosed and the Patent Office charges for filing the above-noted documents, including any fees required under 37 C.F.R. 1.136 for any necessary Extension of Time to make the filing of the attached documents timely, please charge or credit the difference to our Deposit Account No. 15-0030. Further, if these papers are not considered timely filed, then a petition is hereby made under 37 C.F.R. 1.136 for the necessary extension of time. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

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DOCKET NO: 202820US3

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF :
TOMOSHIGE UMEDA, ET AL. : EXAMINER: BASICHAS, A.
SERIAL NO: 09/783,548 :
FILED: FEBRUARY 15, 2001 : GROUP ART UNIT: 3749
FOR: MASK :

APPEAL BRIEF UNDER 37 C.F.R. § 1.192

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

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TECHNOLOGY CENTER R3700

This is an appeal from a Final Office Action mailed September 12, 2003. A Notice of Appeal was timely filed on January 12, 2004.

I. REAL PARTY IN INTEREST

The real party in interest in this appeal is Kao Corporation, having an address at 14-10, Nihonbashi Kayabacho 1-chome, Chuo ku, TOKYO 103-8210 JAPAN.

II. RELATED APPEALS AND INTERFERENCES

Appellants, Appellants' legal representatives, and the Assignees are aware of no appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

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III. STATUS OF THE CLAIMS

Claims 1, 6, 8, 9, and 11-15 stand finally rejected and are herein appealed. Claims 2, 7, and 10 were previously withdrawn from consideration.

IV. STATUS OF THE AMENDMENTS

An Amendment After Final was timely filed on December 3, 2003. In an Advisory Action mailed December 11, 2003, the Examiner indicated that for purposes of appeal the Amendment of December 3, 2003 would be entered. The Advisory Action indicated that an explanation of how the new or amended claims would be rejected was provided therewith. However, no such explanation was attached to the Advisory Action. Consequently, Applicants' representative contacted the Examiner to determine if the explanation had inadvertently been omitted. In response to the Applicants' inquiry, the Examiner issued a Supplemental Advisory Action. However, the Supplemental Advisory Action addressed the Information Disclosure Statement of December 3, 2003, and did not provide any additional explanation regarding the rejection of the amended claims. The attached Appendix I reflects Claims 1, 2, and 6-15 as presently pending on appeal.

V. SUMMARY OF THE INVENTION

The present invention relates to a mask including a heat generating unit incorporated therein, where the heat generating unit generates heat by chemical reaction using an exothermic composition containing a metal powder, salt, and water, and releases steam in conjunction with the oxidation reaction of the metal powder, thereby generating therapeutic vapor or inhalation. In the dry winter season, it becomes very easy to catch a cold. Conventionally, masks have been used as a measure to prevent the common cold by preventing the inhalation of viruses and by keeping the throat warm. One such common

mask is a mask made of folded gauze attached to the wearer by rubber ear loops. However, while conventional masks made simply by folding gauze or the like are effective in retaining heat supplied from body temperature exhalation, such masks have no heating mechanisms in and of themselves, and are unable to actively supply warm steam to the nose or throat. As a result, they are unable to moisten the upper respiratory tract.¹

Conventional masks that incorporate a moisturizing part or a moist part impregnated with water or other substance are not provided with a mechanism that promotes the generation of drug vapors or steam. These vapors in the conventional masks are only promoted by the inhalation action produced by respiration, and it is very difficult to reliably supply moisture or drugs to effectively prevent colds in the upper respiratory tract.² In light of these difficulties, the Applicants developed the present invention. To this end, the Applicants developed the mask, as recited, for example in Claim 1. As recited in Claim 1, a mask includes a heat generating unit incorporated therein, where the heat generating unit generates heat by chemical reaction using an exothermic composition containing a metal powder, salt, and water, thereby generating a therapeutic vapor for inhalation.

With reference to Figures 1A and 1B, the mask includes a heat generating unit (10A), wherein the heat generating unit is configured to generate heat by chemical reaction, wherein the heat generating unit comprises an exothermic composition (11) containing a metal powder, salt, and water, which heat generating unit releases steam in conjunction with oxidation reaction of the metal powder, thereby generating a therapeutic vapor for inhalation.³

Additionally, with regard to Claim 15, Figures 1A and 1B illustrate a mask including a main mask body (3) and heat generating means (10A) for generating steam in the main mask body (3) by an exothermic oxidation chemical reaction.

¹ Specification, page 1, line 20 - page 2, line 15.

² Id. at page 2, lines 16-25.

³ Id. at pages 30-31.

VI. ISSUES

The single issue for review is whether one or more of Claims 1, 6, 8, 9, and 11-15 are unpatentable over Daneshvar (U.S. Pat. No. 5,205,282) in view of Mitra (U.S. Pat. No. 5,890,486).

VII. GROUPING OF THE CLAIMS

For the single issue, Claims 1, 6, 8, 9, and 11-15 stand together.

VIII. ARGUMENT

The Final Office Action explicitly rejects Claims 1, 6, 8, 9, and 11-15 as unpatentable over Daneshvar in view of Mitra.

Independent Claim 1 recites a mask that includes a heat generating unit incorporated therein, wherein the heat generating unit is configured to generate heat by a chemical reaction, wherein the heat generating unit includes an exothermic composition containing a metal powder, salt, and water, which heat generating unit releases steam in conjunction with oxidation reaction of said metal powder, thereby generating a therapeutic vapor for inhalation.

Independent Claim 15 similarly recites a heat generating means for generating steam in the main mask body by an exothermic oxidation chemical reaction, wherein the steam generates a therapeutic vapor for inhalation.

At the outset, in order to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to modify the reference or to combine the reference teachings. Secondly, there must be a

reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.⁴ Additionally, “[t]he teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicants’ disclosure.”⁵

Moreover, as stated in MPEP § 2143.01, “The mere fact that references can be combined or modified does not render the resulting combination obvious unless the prior art also suggests the desirability of the combination.”⁶ Further, “Although a prior art device ‘may be capable of being modified to run the way the apparatus is claimed, there must be a suggestion or motivation in the reference to do so.’”⁷

- A. **Daneshvar and Mitra represent examples taken from distinct and non-analogous arts, whose combination would not have been obvious to one of ordinary skill in the art at the time of the invention.**

The Office Action states at page 3, paragraph 5:

It would have been obvious to one of ordinary skill in the art at the time of the invention to have incorporated Mitra’s teaching of an apparatus including an exothermic chemical reaction having salt water and metal, and including oxidation reaction into the invention disclosed by Danishvar so as to provide for nasal therapy.

However, Appellants respectfully submit that there is simply no motivation to make the applied combination.

First, Daneshvar is directed to a therapeutic nasal inhaler, in which a therapeutic vapor is generated and delivered *for inhalation* in contact with the nasal passages. Mitra, on the other hand, describes a nasal dilator - a device which mechanically expands the nasal passages by application of an external force - further having a thermal element *which does not generate a vapor for inhalation in contact with the nasal passages*.

⁴ See, MPEP. § 2143.

⁵ In re Vaack, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

⁶ (Emphasis in original). In re Mills, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990).

⁷ Id. at 682, 16 U.S.P.Q.2d at 1432.

As stated in MPEP § 2143:

A statement that modifications of the prior art to meet the claimed invention would have been "well within the ordinary skill or the art at the time the claimed invention was made" because the references relied upon teach that all aspects of the claimed invention (something that is not admitted in this case) were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references.⁸

Applicants respectfully submit that "nasal therapy," as set forth in the outstanding Office Action does not provide an adequate motivation to modify the teachings of either Daneshvar or Mitra in the manner proposed. Moreover, the Office Action fails to cite to any specific teachings of Daneshvar or Mitra to support the applied combination.

Therefore, it is respectfully submitted that the outstanding Office Action has based the rejection upon hindsight reconstruction of references from non-analogous fields of art, and has provided no reasonable support for the applied combination of Daneshvar and Mitra.

B. The amended claim limitations were not addressed by the outstanding Final Office Action.

Claims 1, 10, and 15 were amended in the Amendment of December 3, 2003. While the outstanding Office Action entered the Amendment, the newly added claim limitations were not addressed by the Examiner. Accordingly, it is respectfully submitted that based on the record, the pending claims patentably distinguish over the applied combination of Daneshvar and Mitra.

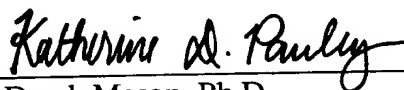
⁸ Ex part Levensgood, 28 U.S.P.Q.2d 1300 (Bd. Pat. App. & Inter. 1993).

IX. CONCLUSION

Appellants submit that the references neither disclose nor suggest the mask recited in Claims 1, 6, 8, 9, and 11-15. Accordingly, it is respectfully requested that all rejections still pending in the Final Office Action be REVERSED.

Respectfully submitted,

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APPENDIX I

1. A mask, comprising a heat generating unit incorporated therein, wherein said heat generating unit is configured to generate heat by chemical reaction, wherein said heat generating unit comprises an exothermic composition containing a metal powder, salt, and water, which heat generating unit releases steam in conjunction with oxidation reaction of said metal powder, thereby generating a therapeutic vapor for inhalation.

2. The mask according to claim 1, having a moisture-retaining unit, separate from said heat generating unit.

3-5. (Canceled)

6. The mask according to claim 1, wherein said heat generating unit is configured to be attached and detached.

7. The mask according to claim 1, further comprising a temperature buffering between said heat generating unit and a face when said mask is donned.

8. The mask according to claim 1, further having a drug carrier unit.

9. The mask according to claim 1, wherein said heat generating unit comprises an exothermic composition with a drug dispersed in said exothermic composition.

10. The mask according to claim 1, further comprising a bag containing the exothermic composition, which bag has a surface adapted to be applied to a face, and which bag comprises a moisture permeable sheet exhibiting a moisture permeability between about $1000 \text{ g/m}^2 \cdot 24\text{h}$ and about $13,000 \text{ g/m}^2 \cdot 24\text{h}$ under conditions of a temperature of 40°C and relative humidity of 90%, and an air permeability of 200 seconds/100 cm^3 or less.

11. The mask according to any one of claims 1-2 and 6-10, wherein main mask body is provided with at least one of an inhalation valve and an exhalation valve.

12. The mask according to claim 11, wherein an inhalation valve and an exhalation valve are provided separately in said main mask body.

13. The mask according to claim 11, wherein an inhalation/exhalation valve is provided in said main mask body.

14. The mask according to claim 1, configured to have a space and distance between said heat generating unit and a face when said mask is donned.

15. A mask comprising:

a main mask body; and

heat generating means for generating steam in said main mask body by an exothermic oxidation chemical reaction.